

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Cayeula et al.  
 Appl. No.: 09/856,969  
 Filed: 08/01/2001  
 For: SELECTION AND USES OF LACTIC ACID BACTERIA STRAINS  
 MODULATING NON-SPECIFIC IMMUNITY



Confirmation No.: 5142  
 Group Art Unit: 1645  
 Examiner: Jana A. Hines

Mail Stop RCE  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
 CITATION UNDER 37 C.F.R. § 1.97**

Attached is a list of documents on form PTO-1449, along with any cited foreign patent documents and non-patent literature documents in accordance with 37 CFR 1.98(a)(2). This art was supplied by our foreign associate after receipt of the Notice of Allowance and is being filed concurrently herewith with a Request for Continued Examination.

It is requested that the Examiner consider these documents and officially make them of record in accordance with the provisions of 37 C.F.R. § 1.97 and Section 609 of the MPEP. By identifying the listed documents, Applicant in no way makes any admission as to the prior art status of the listed documents, but is instead identifying the listed documents for the sake of full disclosure.

Respectfully submitted,

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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment (unless sent with patent application), Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on May 25, 2005.

Janet F. Sherrill

<p>Substitute for form 1449/PTO (Revised 04/2003)</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY EXAMINER</b> <i>(Use as many sheets as necessary)</i></p>				<b>Complete if Known</b>	
				Application Number	09/856,969
				Filing Date	August 1, 2001
				First Named Inventor	Cayuela et al.
				Group Art Unit	1645
				Examiner Name	Jana A. Hines
Sheet	1	of	3	Attorney Docket Number	033339/234602

#### U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
	1	US-5,032,399	07/16/1991	Gorbach et al.	
	2	US-5,413,785	05/09/1995	Nanji	
	3	US-5,591,428	01/07/1997	Bengmark et al.	
	4	US-5,716,615	02/10/1998	Cavaliere Vesely et al.	
		US-			
		US-			

#### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	English Language Translation Attached
	5	EP 0 199 535 A2	10/29/1996	Gorbach et al.		YES
	6	EP 0 861 905 A2	09/02/1998	Pedraglio		YES
	7	EP 0 794 707 B1	09/17/1997	Bouley et al.		NO
	8	WO 98/06411	02/19/1998	Guandalini		YES

#### OTHER DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) , volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
	9	TUOMOLA et al., "Adhesion of some probiotic and dairy <i>Lactobacillus</i> strains to Caco-2 cell cultures", <i>International Journal of Food Microbiology</i> , 41 (1998) pp. 45-51.	YES
	10	YEUNG et al., "Species-Specific Identification of Commercial Probiotic Strains", <i>American Diary Science Association</i> , Vol. 85, No. 5, 2002, pp. 1039-1051.	YES
	11	MAJAMAA, et al., "Lactic Acid Bacteria in the Treatment of Acute Rotavirus Gastroenteritis", <i>Journal of Pediatric Gastroenterology and Nutrition</i> , 1995, pp. 333-338.	YES

Examiner Signature		Date Considered	
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

MAY 25 2005

**INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 3

**Complete if Known**

Application Number	09/856,969
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First Named Inventor	Cayuela et al.
Group Art Unit	1645
Examiner Name	Jana A. Hines

Attorney Docket Number 033339/234602

**OTHER DOCUMENTS**

12	MIETTINEN et al., "Production of Human Tumor Necrosis Factor Alpha, Interleukin-6, and Interleukin-10 is Induced by Lactic Acid Bacteria", <i>Infection and Immunity, American Society for Microbiology</i> , December 1996, pp. 5403-5405.	YES
13	COLLINS, et al., "Deoxyribonucleic Acid Homology Studies of <i>Lactobacillus casei</i> , <i>Lactobacillus paracasei</i> sp. Nov., subsp. <i>Paracasei</i> and subsp. <i>tolerans</i> , and <i>Lactobacillus rhamnosus</i> sp. Nov., comb. Nov." <i>International Journal of Systematic Bacteriology</i> , April 1989, pp. 105-108.	YES
14.	KAILA et al., "Viable versus inactivated lactobacillus strain GG in acute rotavirus diarrhea", <i>Archives of Disease in Childhood</i> , 1995, pp. 51-53.	YES
15	PERDIGON et al., "Immunoadjuvant activity of oral <i>Lactobacillus casei</i> : influence of dose on the secretory immune response and protective capacity in intestinal infections", <i>Journal of Dairy Research</i> (1991), PP. 485-496.	YES
16	SHIBOLET, et al., "Variable Response to Probiotics in Two Models of Experimental Colitis in Rats", <i>Inflammatory Bowel Diseases</i> , 2002, pp. 399-406.	YES
17	VSL #3 product information, <a href="http://www.vslpharma.com">www.vslpharma.com</a>	YES
18	ISOLAUERI et al., "Oral Bacteriotherapy for Viral Gastroenteritis", <i>Digestive Diseases and Sciences</i> , Vol. 39, No. 12 (December 1994), pp. 2595-2600.	YES
19	MAJAMAA et al., "Probiotics: A novel approach in the management of food allergy", <i>J Allergy Clin. Immunol</i> , Vol. 99, No. 2, pp. 179-185.	YES
20	BILLER, et al., "Treatment of Recurrent <i>Clostridium difficile</i> Colitis With <i>Lactobacillus GG</i> ", <i>Journal of Pediatric Gastroenterology and Nutrition</i> , 1995, pp. 224-226.	YES
21	MALIN et al., "Promotion of IgA Immune Response in Patients with Crohn's Disease by Oral Bacteriotherapy with <i>Lactobacillus GG</i> ", <i>Ann Nutr Metab.</i> , 1996, pp. 137-145.	YES
22	PELTO et al., "Probiotic bacteria down-regulate the mild-induced inflammatory response in milk-hypersensitive subjects but have an immunostimulatory effect in healthy subjects", <i>Clinical and Experimental Allergy</i> , 1998, Vol. 28, pp. 1474-1479.	YES
23	KORHONEN et al., "Induction of Nitric Oxide Synthesis by Probiotic <i>Lactobacillus rhamnosus</i> GG in J774 Macrophages and Human T84 Intestinal Epithelial Cells", <i>Inflammation</i> , Vol. 25, No. 4, August 2001, pp. 223-232.	YES
24	ISOLAUERI et al., "Probiotics: effects on immunity", <i>Am J Clin Nutr</i> , 2001, 73 (suppl) pp. 444S-450S.	YES
25	BLACKLOW et al., "Viral Gastroenteritis Agents", <i>Viruses, Rickettsiae, and Chlamydiae</i> , pp. 805-812.	YES
26	DUGAS et al., "Regulation by Endogenous Interleukin-10 of the Expression of Nitric Oxide Synthase Induced After Ligation of CD23 in Human Macrophages", <i>Cytokine</i> , Vol. 10, No. 9, September 1998, pp. 680-689.	YES
27	RACHMILEWITZ et al., "Enhanced colonic nitric oxide generation and nitric oxide synthase activity in ulcerative colitis and Crohn's disease", <i>NO generation for IBD</i> , 1995, pp. 718-723.	YES

Examiner Signature

Date Considered

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Substitute for form 1449 PTO (Revised 04/2003)			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			
(Use as many sheets as necessary)			
Sheet	3	of	3
Attorney Docket Number 033339/234602			
<b>OTHER DOCUMENTS</b>			
28	RACHMILEWITZ et al., "Experimental colitis is ameliorated by inhibition of nitric oxide synthase activity", <i>Gut</i> , 1995, 37, pp. 247-255.		
29	KOLIOS et al., "Expression of inducible nitric oxide synthase activity in human colon epithelial cells: modulation by T lymphocyte derived cytokines", <i>Gut</i> , 1998, 43, pp. 56-63.		
30	ALVAREZ et al., "Immune system stimulation by probiotics", <i>J Dairy Sci.</i> , July 1995, 78(7), pp. 1597-1606.		
31	PERDIGON et al., "Systemic augmentation of the immune response in mice by feeding fermented milks with <i>Lactobacillus casei</i> and <i>Lactobacillus acidophilus</i> ", <i>Immunology</i> , 1988, 63, pp. 17-23.		
32	TEJADA-SIMON et al., "Ex Vivo Effects of Lactobacilli, Streptococci, and Bifidobacteria Ingestion on Cytokine and Nitric Oxide Production in a Murine Model", <i>Journal of food Protection</i> , Vol. 62, No. 2, 1999, pp. 162-169.		
33	ALICAN et al., "A critical role for nitric oxide in intestinal barrier function and dysfunction", <i>American Physiological Society</i> , 1996, pp. G225-G237.		
34	TEPPERMAN et al., "Nitric Oxide Synthase Activity, Viability and Cyclic GMP Levels in Rat Colonic Epithelial Cells: Effect of Endotoxin Challenge", <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 271, No. 3, 1994, pp. 1477-1482.		
35	KORPELA et al., "Lactobacillus rhamnosus GG shows antioxidative properties in vascular endothelial cell culture", <i>Milchwissenschaft</i> , 52(9), 1997, pp. 503-505.		
36	DENARIAZ et al., "Immunity and Probiotics", entire manual, 1999.		
37	DUGAS et al., "Immunity and Probiotics", <i>Trends Immunology Today</i> , Sept. 1999, Vol. 20, No. 9, pp. 1-4.		
38	ISOLauri, Erika, "Promotion of IgA Immune Response in Patients with Crohn's Disease by Oral Bacteriotherapy with <i>Lactobacillus GG</i> ", <i>Ann Nutr Metab</i> , 1996, 40, pp. 137-145.		
39	ISOLauri, et al., "A Human <i>Lactobacillus</i> Strain ( <i>Lactobacillus Casei</i> sp strain GG) Promotes Recovery From Acute Diarrhea in Children", <i>Pediatrics</i> , Vol. 88, No. 1, July 1991, pp. 90-97.		
40	DUGAS et al., "Nitric oxide production by human monocytes: evidence for a role of CD23", <i>Immunology Today</i> , Vol. 16, No. 12, 1995, pp. 574-580.		
41	Danone World Newsletter, October 1995.		
42	SOLIS PEREYRA et al., "Induction of Human Cytokines By Bacteria Used in Dairy Foods", <i>Nutrition Research</i> , Vol. 13, 1993, pp. 1127-1140.		
43	EP Communication for Application No. 00909291.7.		
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